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ORTHOPAEDIC SURGERY

A new universal, standardized implant database for product identification: a unique tool for arthroplasty registries

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Abstract

Introduction Every joint registry aims to improve patient care by identifying implants that have an inferior performance. For this reason, each registry records the implant name that has been used in the individual patient. In most registries, a paper-based approach has been utilized for this purpose. However, in addition to being time-consuming, this approach does not account for the fact that failure patterns are not necessarily implant specific but can be associated with design features that are used in a number of implants. Therefore, we aimed to develop and evaluate an implant product library that allows both time saving barcode scanning on site in the hospital for the registration of the implant components and a detailed description of implant specifications.

Materials and methods A task force consisting of representatives of the German Arthroplasty Registry, industry, and computer specialists agreed on a solution that allows barcode scanning of implant components and that also uses a detailed standardized classification describing arthroplasty components. The manufacturers classified all their components that are sold in Germany according to this classification. The implant database was analyzed regarding the completeness of components by algorithms and real-time data.

Results The implant library could be set up successfully. At this point, the implant database includes more than 38,000 items, of which all were classified by the manufacturers according to the predefined scheme. Using patient data from the German Arthroplasty Registry, several errors in the database were detected, all of which were corrected by the respective implant manufacturers.

Conclusions The implant library that was developed for the German Arthroplasty Registry allows not only on-site barcode scanning for the registration of the implant components but also its classification tree allows a sophisticated analysis regarding implant characteristics, regardless of brand or manufacturer. The database is maintained by the implant manufacturers, thereby allowing registries to focus their resources on other areas of research. The database might represent a possible global model, which might encourage harmonization between joint replacement registries enabling comparisons between joint replacement registries.

Keywords Joint register · Implant database · German arthroplasty registry · Total hip arthroplasty · Total knee arthroplasty · EPRD

For the German Arthroplasty Registry Implant Library Task Force.

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Introduction

Given the profound improvements of total hip or total knee arthroplasty on patients health-related quality of life, it is not surprising that total knee arthroplasty has been named the "joint of the decade" [1] and total hip arthroplasty has been named the "operation of the century" [2].

The importance of arthroplasty registries has been well established: while most patients are very satisfied after surgery, some patients have outcomes that are well outside of what would be regarded as acceptable. In this respect, many countries have high rates of revision surgery, such as 18 % in the United States or 13 % in Germany [3]. However, several countries were able to significantly reduce their revision rates by the implementation of national joint registries: Sweden was able to drop its revision rate from 16 to 8 % [4], Australia from 16 to 12 %, and England from 13 to 10 %. It has been concluded that registries are "among the most cost-effective interventions in medicine" [5].

Joint replacement registries play an important role in providing quality post-market surveillance and help understand implant and surgery failure mechanisms, reasons for revisions, and how to improve patient outcomes [6, 7]. This has motivated several other countries, such as Canada, Denmark, France, Italy, the Netherlands, New Zealand, Norway, Portugal, Scotland, and Slovakia to establish national joint registries. In the United States, the American Joint Replacement Registry AJRR was founded in 2008.

Although patient-related factors may influence the need for revision surgery, some revisions are related to implant problems. Identifying implant-related failures is one of the key issues of joint registries [8]. For this reason, each registry has to link patient revision data to implant data. In order to accomplish this, each registry created its own implant database.

Setting up such an implant database is quite complex. As a first step, the implant lists are entered into the implant database by the different manufacturers. Once the registry becomes aware of new implants introduced to the market, these implants are manually added to the database.

The link between patient data and the implant database is handled differently in the existing registries. In most registries, implant identifying stickers are attached along with patient identifying data to a paper form which is then centrally entered into the registry. This off-site and sometimes manually performed registration, however, is both error-prone and time-consuming. An on-site registration using barcode scanning of implant identification stickers would greatly enhance the registration process.

Implant outcome patterns are not necessarily implant-specific but can be associated with design features that are used in a number of implants. For example, the experiences with the metal-on-metal in total hip arthroplasty (THA) showed that not only the implant but also material and size matter in terms of revision rate [9, 10]. Another example is the corrosion in modular neck-stem taper junction in THA, which also resulted in recalls of certain conspicuous implants [11, 12]. Therefore, it is crucial that the implant database is able to group implants according to characteristics, such as design features or tribological combinations.

For these reasons, we aimed to develop an implant product library that incorporates on-site barcode scanning of the implant components in the hospital, including a detailed description of implant specifications for a subsequent detailed implant analysis.

Methods

We established a task force consisting of representatives of the registry, implant manufacturer, and computer specialists. The members of this task force met many times over the course of 3 years and agreed on a solution that incorporates the following requirements: (a) on-site barcode scanning of implant components in the hospital; (b) a classification scheme that allows the description of arthroplasty components in great detail across implant families; (c) application of the definitions to all implants in the database.

The classification scheme was forwarded to the implant companies who classified all their components that are sold in Germany, accordingly. Parts of the merged library were put online for use with the barcode scanning software of the German Arthroplasty Registry. We used algorithms and real-time data from the EPRD, e.g., regarding the completeness of components, to analyze the implant database for possible errors.

The classification scheme is based on the International Standardization Organization (ISO) 7206-1, 2008 (Implants for Surgery—Partial and Total Hip Joint Prostheses—Classification, Definitions and Designation of Dimensions) and ISO 7207-1, 2007 (Implants for Surgery—Partial and Total Knee Joint Prostheses—Classification, Definitions and Designation of Dimensions) [13, 14] (Fig. 1). That classification was originally developed to standardize the different technologies and design features in total joint replacement with respect to be used in registries.

As the ISO classification was not detailed enough for the requirement of the arthroplasty register, we have extended and advanced the classification to achieve a higher granularity, e.g., to classify design features in higher detail.

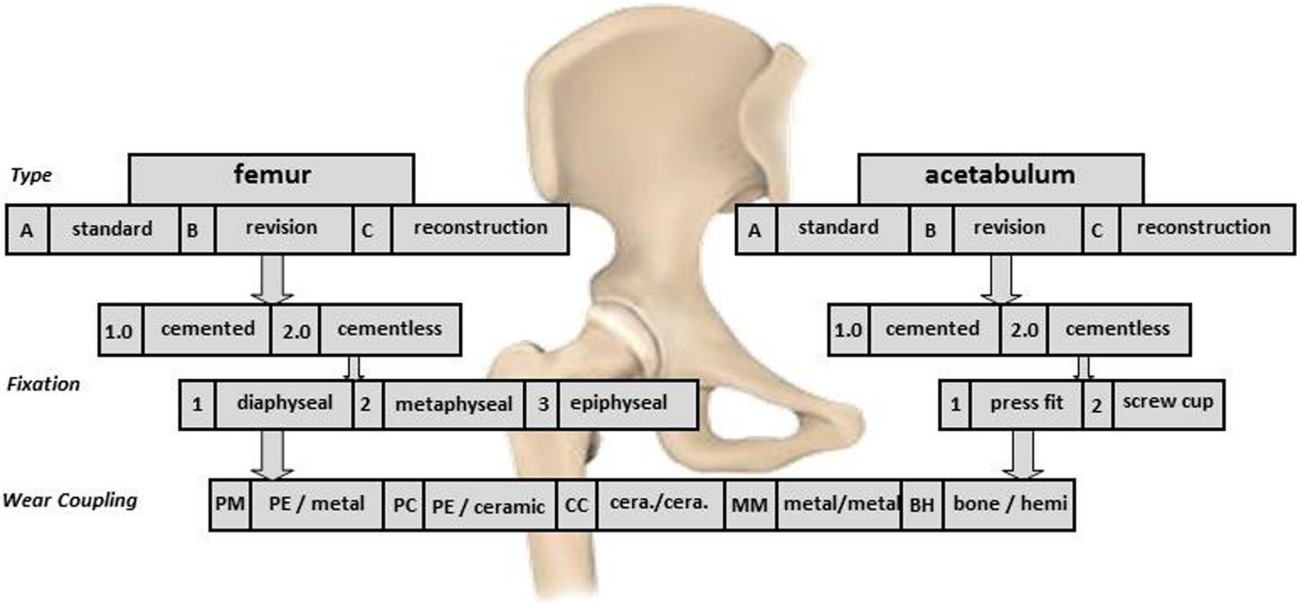

Fig. 1 Basic hip implant classification: ISO 7206-1 (2008) Implants for Surgery—Partial and Total Hip Joint Prostheses—Classification, Definitions and Designation of Dimensions

Results

The universal implant classification developed for the EPRD is based on the international standards ISO 7206-1 (2008) and ISO 7207-1 (2007) [13, 14]. Other known systems for description and classification, such as the Universal Medical Device Nomenclature System (UMDNS) and the Global Medical Device Nomenclature (GMDM), have been checked for use in registries and were regarded as not sufficient in granularity for the purpose of an arthroplasty registry.

The classification developed allows differentiating every implant component according to type, material, fixation, type of coatings, and design criteria. These classification groupings are stored together with the device identification data given by the Global Trade Identification Number (GTIN) and the brand name in the implant database. If required, the full granular level can be used. On the other hand, a minimum set of variables necessary for risk adjustment and outcome evaluation is available.

Details of our classification system are shown in the Online appendix.

Through the commitment of all local implant manufacturers to classify all implant components and implement and maintain the database, the implant library was created as a web-based master data library (Fig. 2, Online appendix).

The implant database serves as a reference database for the German Arthroplasty Registry. All implant components in the field of hip and knee arthroplasty from all implant member companies of the German Medical Technology Association (BVMed) along with their specific characteristics as described in the classification section are indexed in this database. The database is continuously updated by the member companies of the BVMed and, in the meantime, also by several other implant manufacturers. Nevertheless, the implant database is open for all implant manufacturers and all implant components, e.g., used in different geographical areas.

All components of hip and knee arthroplasty, with the exception of custom made and accessory implants like non-implant-related screws, pins, and wires are part of the database.

The core component of the implant database is an index of the hip and knee implant components available from the corresponding implant company. Basically, one has to differentiate between the core information that is used for the identification of the implant component (manufacturer, catalog number, barcode information and product name) and other data fields which define the components exactly. Reference for identification of the implant components is the GTIN.

The database has a direct interface with the implant manufacturers. Manufacturers are fully responsible for the completeness of the product components and the correct classification. The database can be updated either by a web front-end for the direct acquisition and maintenance of the individual data sets or by specific software solutions for user-friendly import/export functions and mass data transports. The complete content of the database is provided to

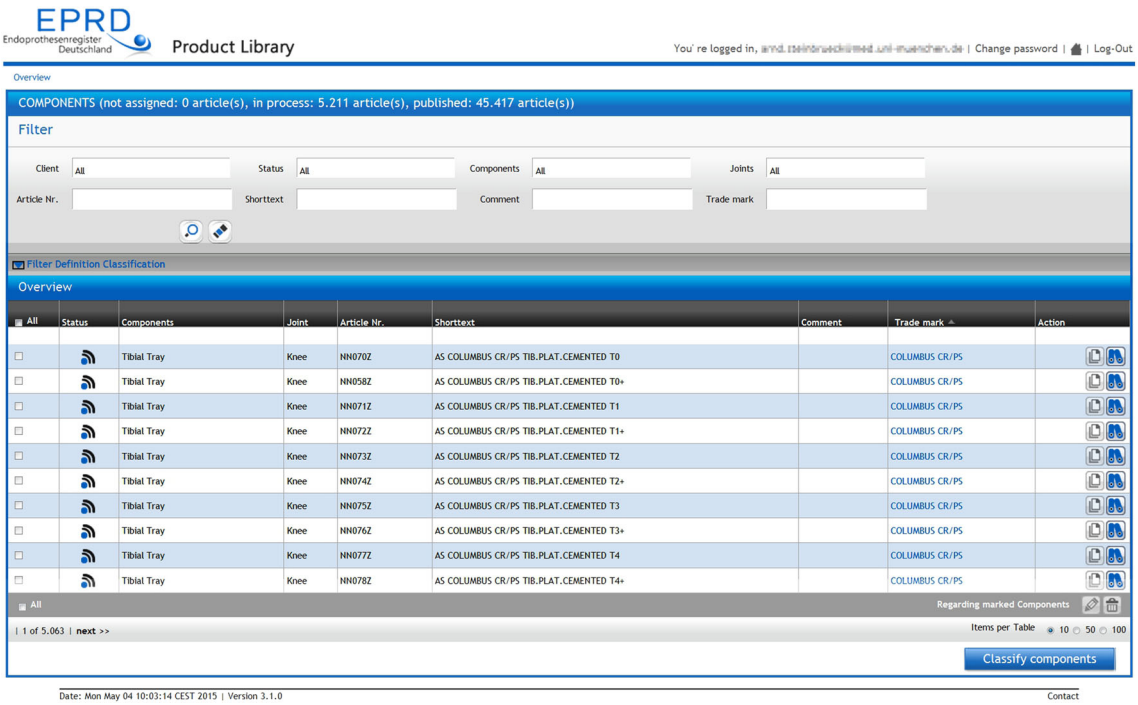

Fig. 2 Web-based implant data library "http://www.arthroplastylibrary.org". The shown product identification part of the implant data base is followed by a product classification part

the EPRD at regular intervals over a specific web service interface. To date, more than 38,000 single components of hip and knee implants have been classified and added to the library (Fig. 3; Table 1).

Parts of the merged library were set online for use with the barcode scanning software of the German Arthroplasty Registry (EPRD). As a standard procedure, implants are scanned by means of a barcode reader in the operating room of the hospital. In the process, different barcodes systems, e.g., GS1, EAN, or HIBC, using the GTIN are taken into account allowing for the unambiguous identification of the implant and matching the barcode with the information contained in the implant database. By scanning the Device Identifier (DI) to identify the implant component in the implant database and the Production Identifiers (PI) composed of the lot or batch number, the serial number, the expiration date, and the manufacturing date from the device barcode, the Unique Device Identifier (UDI) information is available for the register analysis at any time.

Implant components used are identified through collation with the product database using specific developed software and stored in the register along with the data pseudonyms of the individual patient. The dataflow was developed in agreement with the federal data security engineer of Germany to exclude a personal data acquisition. In fact, personal data of patients are encoded in a way that even the Registry is not able to trace these data back to the patient without the help of the hospital or the insurance companies.

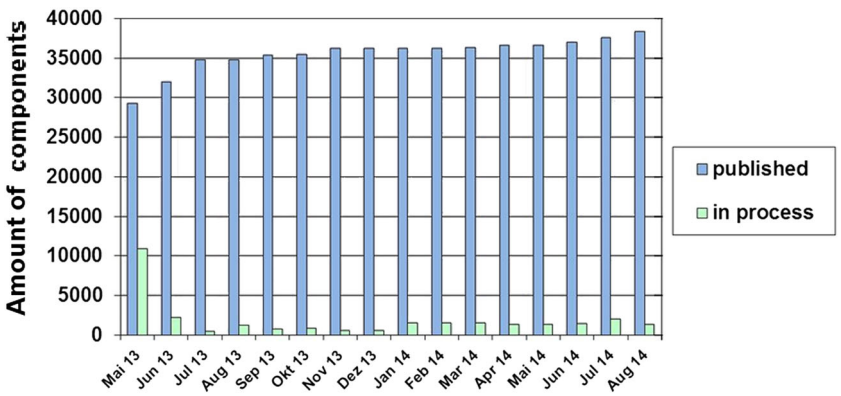

Fig. 3 Status of input to the implant database from 18 implant manufacturers (September 2014)

Table 1 Status of input from Implant manufacturers as of August 31, 2014 to the German Arthroplasty Register Product Database

B. Braun Aesculap AG	4.485 Art. published, 1 Art. in process
Biomet Deutschland GmbH	3.462 Art. published, 576 Art. in process
CeramTec AG	144 Art. published
Corin Germany GmbH	936 Art. published, 101 Art. in process
DePuy Orthopadie GmbH	4.819 Art. published
Heraeus Medical GmbH	45 Art. published
Implantcast GmbH	4.104 Art. published, 13 Art. in process
Mathys Orthopadie GmbH	1.679 Art. published
Merete Medical GmbH	146 Art. published, 2 Art. in process
Peter Brehm GmbH	742 Art. published
Smith & Nephew GmbH	6.055 Art. published
Stryker GmbH	2.419 Art. published, 71 Art. in process
Symbios Deutschland GmbH	396 Art. published
Waldemar Link GmbH & Co.KG	2.338 Art. published
Zimmer Germany GmbH	5.344 Art. published
Wright Medical	599 Art. published, 1124 Art. in process
Total	38.345 Art. published, 1311 Art. in process

We used algorithms and real-time data from the German Arthroplasty Registry, e.g., regarding the completeness of components and real health care data or regarding the correct classification of the implants to analyze the implant database for possible gaps and errors. As of July 21, 2014, there were 135,223 articles that were documented for the 35,013 surgeries in the registry. Of these, there were 123,520 articles that could be identified within the implant library. As of July 21, 2014, only 7767 articles of the 36,290 articles in the implant database have been used by the surgeons participating in the registry so far. That means that on the average, each article in the implant library was documented 17 times, of which 11 articles were documented more than 500 times. The most frequently registered article was documented 803 times.

We have developed algorithms that classify the combination of implants registered for each individual patient either as correct, not complete, or over-complete. In this respect, we could identify several gaps in the database.

The first example (Table 2) involves an Apex Hole Eliminator that was not included in the implant library right from the start but was added later on. This Apex Hole Eliminator was in the implant database with its secondary article number and was named "DURALOC OPTION Press Fit-Cup, Outer diameter 54 mm, Porocoat®, 3 Holes" and was classified as a cup. Therefore, the above-mentioned surgery was classified as having two cups and was assigned the status "over-complete." In the meantime, the implant manufacturer has corrected this error.

The second example involves a ceramic head which material was classified as titanium by mistake. This error in the implant database was detected when we listed the tribological pairings used. In this list, several cases were classified as having a metal on ceramic articulation, which is obsolete. The workup of these cases resulted in the identification of the erroneously named material Titanium for the head made of ceramic. One of these cases that resulted in the identification of this error is shown in Table 3.

Discussion

Joint replacement registries are in essence part of a continuous quality assurance effort in which patients at risk are followed; good devices, techniques, and hospitals are promoted; risk factors are identified; and actions are taken to achieve the best possible result for the individual patient. Registries enable evaluations that are based on clinical evidence. Registries offer opportunities for research and they help health care providers by providing them with their own balanced and trustworthy clinical data. Given the tremendous advantages of arthroplasty registries, it has even been stated that registries are part of the orthopedics profession's "ethical duty to serve patients and the community" [15].

Table 2 Example for an "over-complete" registration of implants in the implant database

Article number	Characteristic	Charge
0603295014348	ACETABULAR LINER +4 NEUTRAL 32 mm ID 54 mm OD	340998
0603295019688	Apex Hole Eliminator	D13032331
121722054	PINNACLET Press Fit-Cup Sector, OD 54 mm, with 3 holes, Porocoat®	282692
0603295359166	Biolox Forte Ceramic Femoral Head +9, 32 mm 12/14 Taper	3576173
L20312	CORAILT AMT-femoral stem, Sz. 12, length 150 mm, Hydroxylapatit-Coating, High Offset, lateralised, (KHO), without	5115765

Table 3 Example for an incorrect classification of an implant material in the implant database

Description	Art-Nr	Characteristic	Value
Head Ceramic 32/14 M BIOLOX	19632	Design	Regular
		Length	Medium (reference)
		Material	Titanium
		Size	32

However, quality and completeness of the raw data are fundamental to all analysis. Comparing data of different joint registries can be crucial in general and can be misleading [16, 17], especially when comparing implant types or designs without accounting for confounding factors, such as indications for surgery, specific techniques used, or standardized classification parameters for implant components. The German Arthroplasty Registry (EPRD), however, enables an in-depth analysis of the effects of these factors.

This is achieved by a universal and standardized implant database that was developed during the setup of the German Arthroplasty Registry. In that implant database, specifications of each implant component are described in detail. Moreover, for the ease of the users who do the registration work in the hospital, it allows on-site barcode scanning of the implant components.

In contrast to regulated drugs, there is no universally accepted nomenclature for medical devices and in particular for orthopedic implants. Instead, various stakeholders have developed disparate ways to classify devices, such as Product Codes, the UMDNS, and the GMDM system [7, 13].

In the past, several orthopedic registries have also created their own classifications based on the names of implant manufacturers, catalog numbers, and/or brand names. Classification schemes for the attributes of prosthesis components vary as well. They were usually developed without a global approach reflecting the most relevant scientific research questions of the time when developed, e.g., implant fixation methods, metal-on-metal bearings, and head sizes. Critical issues include historical changes in prosthesis design that were not accompanied by device name change or catalog number change [7, 18, 19].

When using catalog or lot numbers for creating a classification, the lack of standardization and the lack of categorization into attributes and characteristics limits the usability for other registries. In addition, it also limits the consistency of reporting between registries. According to Sedrakyan [7], the percentage of registries collecting information on fixation and implant characteristics varies between about 40 % (short description of the implant) and about 90 % (manufacturer, catalog number and cemented/uncemented fixation).

Although we currently have more than 37,000 surgeries in the EPRD, less than 6000 of the more than 38,000 implants in the implant database have been utilized in the patients of the registry yet.

As Germany did not have a working arthroplasty registry in the past, we were fortunate that we did not have to be compatible with earlier databases. Thus, we were able to design the German Arthroplasty Registry and its implant library from scratch, allowing us to take advantage of the current information technology available, without being limited by data structures from the past that have been developed before modern information technology became available. Although this is a strength of our database, it could be regarded as a limitation by existing registries, as they might be constricted by their established registry specific data structure, which might not allow them to adapt the implant library introduced here without major modifications to their own database.

There have been several attempts to set up an arthroplasty registry in Germany. The German Association of Orthopaedics and Orthopaedic Surgery (DGOOC) had been trying to establish an arthroplasty register for nearly two decades. From 1997 to 2004, the "German Arthroplasty Register Association" has collected arthroplasty data on a voluntary basis using manual documentation [20]. That register was discontinued, at least due to lack of systematic funding. Subsequently, comprehensive concepts were drawn up to set up a statutory Arthroplasty Registry organized through an already existent compulsory external quality assurance program. In 2009, after the German External Quality Provider had been changed, the implementation of a National Arthroplasty Register could no longer be expected to be realized in the short to medium term. Therefore, in 2010, the DGOOC founded the German Arthroplasty Registry (EPRD). The EPRD is a not-for-profit society and a subsidiary of the DGOOC. Structured cooperation was built up by overcoming long existing boundaries between the orthopaedic scientific society, the arthroplasty and implant division within the German Medical Technology Association (BVMed), the health insurers, and the hospitals [17, 21–23]. The BQS-Institute for Quality and Patient Safety was integrated in the cooperation as scientific partner and at the same time provider of the registry system and information technology.

The EPRD aims to record the implant survival times across the nation. The results will be made accessible to the scientific community and to the general public by regular evaluations, publications, and presentations. Data collection in the German Arthroplasty Registry is organized with the aim to keep additional administrative burdens at a minimum, which was an essential goal of the project, and

strictly adheres to the existing data protection regulations. This is accomplished by the use of routine accounting data and arthroplasty implantations and revisions that is collected by the hospitals for reimbursement purposes anyway. These data are forwarded to the register as part of the routine accounting procedures between the hospitals and the health insurance providers.

A struggle for every national registry is participation and the compliance for recoding revisions. Even in countries where participation of the hospitals in the national registries is mandatory, a low coding morale and subsequent quality of recording of revision surgery is described [24]. For reimbursement purposes, all hospitals in Germany have to code their diagnoses using the International Statistical Classification of Diseases and Related Health Problems (ICD 10) System and have to code their surgeries using the "Operationen- und Prozedurenschlüssel" (OPS) 301 system [25], in which OPS is the German modification of the International Classification of Procedures in Medicine (ICPM). Additionally, the type of operation (primary, exchange, addition, or removal of implants) is registered in the implant online-registration tool. The coding is a requirement for reimbursement for the hospitals by the insurance companies. Since the German Arthroplasty Registry is embedded in a system of various stakeholders, including the health-insuring companies, we were able to arrange that ICD 10 and OPS 301 information on all subsequent surgeries after the primary registration is automatically forwarded to the Registry. Therefore, the German Arthroplasty Registry gets all information on subsequent surgeries and is not dependent on the coding morale of the surgeons.

Conclusion

The implant library developed for the German Arthroplasty Register (EPRD) is unique in several ways. First, it allows on-side barcode scanning for the registration and identification of the implant component. Second, the classification which has been performed by the implant manufactures allows sophisticated analysis regarding implant characteristics, regardless of brand or manufacturer. Third, the database has been implemented and is maintained by the implant manufacturers, thereby allowing registries to focus their resources on other areas of research. Fourth, if the database was accepted as a global model, it would encourage harmonization between joint replacement registries. Fifth, the standardized implant classification system described here advances future scientific research, e.g., on implant modularity or advanced surface coatings. This is strongly needed, as it enhances total joint arthroplasty research collaboration worldwide and is one step forward in order to enable comparisons between joint replacement registries.

Conflict of interest None.

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